KARDiVAR.TV

KARDiVAR system
for stress level evaluation

User's Guide

Read Me First

Rev. 1.0

Warnings

- Use IEC60601-1-1 standard to combine the KARDiVAR system with other devices (computers and peripherals), see chapters 4.1 and 4.2.
- Do not operate KARDiVAR system within 3 meters of an operating cellular phone, similar radio transmitting device, other powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, x-ray machines, or any other equipment that produces electrical sparks (see chapter 6.3).
- Reusable electrodes present a potential risk of cross-infection especially when are used on abraded skin, unless they are restricted to a single patient or sterilized between patients. The sterilization recommendations from electrode producer should be used.
- Explosion Hazard. Do not use the KARDiVAR system in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.
- Do not immerse the any parts of KARDiVAR system in water.
- Take care of the system's components. Avoid the cables' breaks, kinks, tension and other mechanical efforts.
- Take care of arranging Patient and USB cables/wires to avoid the risk of patient entanglement or strangulation.
- The operator is responsible to ensure the safety of any devices controlled or triggered by any software or hardware receiving data from the KARDiVAR system. And this system must not be configured or connected in such a way that failure in its data acquisition, processing or control functions can trigger patient feedback stimulus that poses an unacceptable level of risk.
- Use the special ECG electroconductive gel/paste for the ECG acquisition.
- Do not spread the electroconductive gel/paste on wounded or scarred skin.
- The KARDiVAR system is intended for screening analysis of the ECG signals only for adults. It is not suitable for children up to the age of 18 years old. The system can be used for children and teenagers up to age 12-18 years old only for monitoring the tendencies in dispersive parameter changes. For children and teenagers the use of the system is determined by the doctor in each specific case.

- The KARDiVAR system does not diagnose! The system functions to define index of regulatory system activity by a heart rate variability analysis and inform about the presence of the deviations. The KARDiVAR system is not a substitute the other clinical methods of heart diagnostics; it gives the additional information about the heart rate variability.
- The drug taking can influence on the accuracy of the index of regulatory system activity and forming the conclusion and comments. If the system is used during the drug treatment it is necessary to compare the current data with the data collected before the drug taking.

Manufacturer and representatives

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Medical device concerned

Name of product:	*KARDiVAR system*
Classification:	*Class IIa*
Rule(s) used for classification:	*Annex IX of MDD 93/42/ECC, rule 10*
Notified Body:	*Eurocat (0535)*

Document number: 4166.

The manufacturer has the right to alter this document according to the changes made by manufacturer for improving the system.

Print errors which may be presented in this guide will be corrected in future editions.

Document revision history:

Revision	Comments
1.0	Original Release

Contents

Symbols on labels

Symbol	Meaning
	Electrical medical device, CLASS II EQUIPMENT.
	Electrical medical device, TYPE CF with defibrillator protection.
	Attention. Carefully read specification or instruction for use.
	This device conforms to Directive 93/42/EEC.
	USB connector.
	Serial number.
	Date of manufacturing.
	Separate collection with electrical and electronic equipments for recycling.

Abbreviations

Term	Meaning
CPU	Central processing unit
DC	Direct current
ECG	Electrocardiogramm
EMC	Electromagnetic compatibility
IRSA	Index of regulatory system activity
LED	Light emitting diode
MCS	Medical Computer Systems, Ltd
OS	Operational system
PC	Personal computer
RF	Radio frequency
USB	Universal serial bus

1. Main features

1.1 Intended use

The KARDiVAR is a computer system for stress level evaluation by a heart rate variability analysis utilize up to 6 standard ECG leads.

This system contains the **PC-ECG module KARDi2/4** and the **VARICARD-KARDi software** that converts the ECG leads to heart rate variability parameters and calculate the stress level.

The KARDiVAR system will avail for medics, psychologists, staff managers, special agents, the fitness industry, sports teams and emergency medical facilities.

1.2 Basic Functionality

The basic features of the KARDiVAR system are:

1. the 5 minutes ECG acquisition of the 6 standard leads (I, II, III, aVR, aVL, aVF) by KARDi2/4, analyzing and visualization;
2. heart rate variability analyzing and creating index of regulatory system activity (later the *IRSA*) where a stress level indicator is displayed as the "Traffic light";
3. analyzing and visualization basic heart rhythm variability parameters;
4. the conclusion and comments creating.

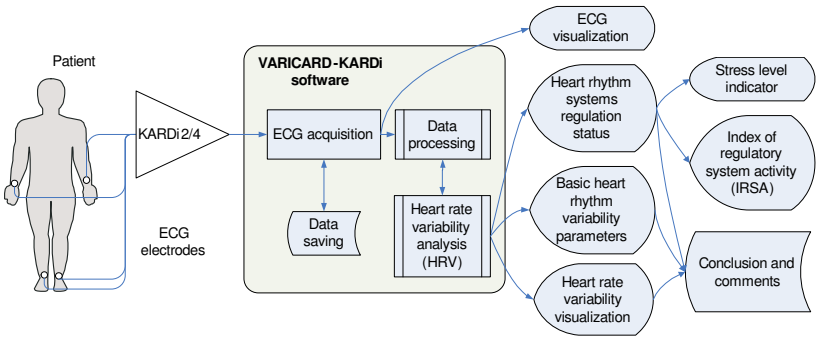


Fig.1 The basic features' diagram of the KARDiVAR system.

1.3 Classification

The KARDiVAR system is a *Class IIa* device according to Council Directive 93/42/EEC for medical devices.

The system is classified for CLASS II TYPE CF EQUIPMENT according to IEC 60601-1 (protection against electric shock).

The system classified by CISPR 11 standard as a Group 1, Class B equipment according to IEC 60601-1-2 (electromagnetic compatibility). For more information about EMC see chapter 6.3.

2. General information

2.1 Packaging

The following items form the whole package:

1. PC-ECG module KARDi2/4 with fixed USB cable.
2. Clamp ECG electrodes (see chapter 4.3).
3. The CD disk with driver and VARICARD-KARDi software.
4. KARDiVAR system. User's Guide (this document).
5. VARICARD-KARDi. User's manual.
6. Special fastener for the system fixation (see chapter 3.3).
7. *Optional* PC and/or printer.
8. Case for all aforementioned items.

2.2 Warranty, service life and utilization

The system and all equipment according to the chapter 2.1, excluding the ECG electrodes, special fastener and case, are guaranteed to be free from defects in material and workmanship for 24 months from the date of purchase.

In the unlikely events that repair is necessary, call the manufacturer representative to receive a Return Authorization. Then send the unit back by a traceable method – the manufacturer representative is not responsible for not received items. We will repair or replace your unit(s) free of charge.

This warranty does not apply to damage incurred through accident, alteration or abuse.

The KARDiVAR systems' average service life is not less than 5 years if the mean time of system's operating does not exceed 80 hours per month.

Utilize the system according to your regional laws. In the European Union use the requirements of the Directive 2002/96/EEC for the system utilization.

2.3 Maintenance

Regularly use surface disinfectants, but not less than one time in the month. For material compatibility use the disinfectants based on the alcohol.

Factory testing and calibration ensure equipment accuracy and frequency response during the whole system's life cycle. If necessary, contact the manufacturer representative for factory re-calibration.

3. Installation

3.1 Hardware installation

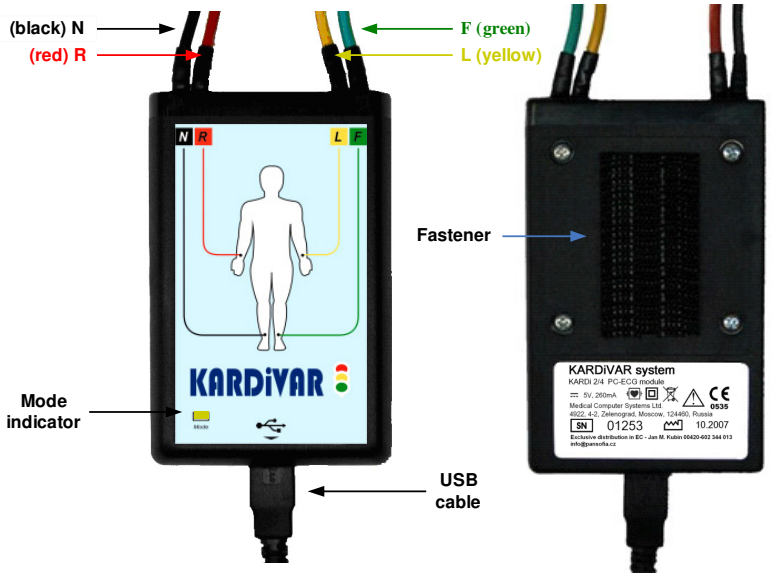


Fig.2 The KARDi2/4 PC-ECG module:
left picture – the front side, right picture – the back side.

1. Unpack the package and check that all parts of the system according to the chapter 2.1 have been received and are undamaged.

   The face of PC-ECG KARDi2/4 module is showed on the left picture, the back side is showed on the right one.

2. Fixate the KARDi2/4 PC-ECG module on the surface using the special fastener (see chapter 3.3).

3. Turn on the PC and wait till the Windows OS will be loaded. Make sure that the PC meets the requirements of the chapters 4.1 and 4.2.

4. Insert the CD disk with driver and VARICARD-KARDi software in the CD-ROM.

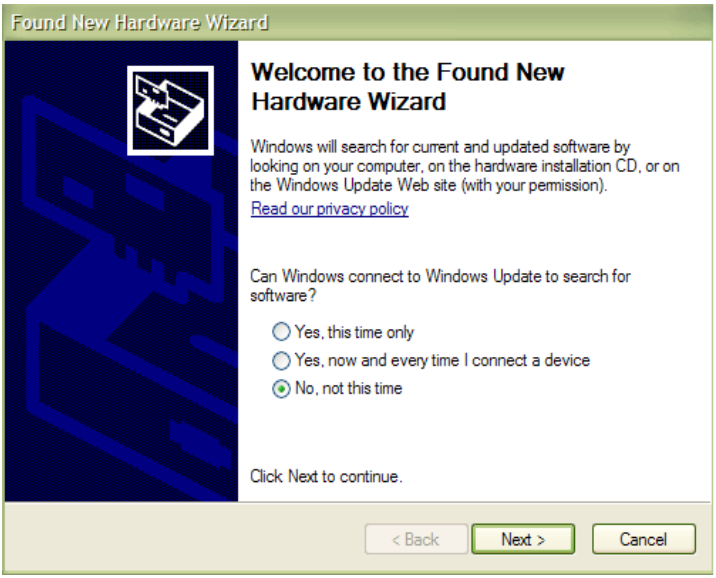
5. Plug the USB cable of the KARDi2/4 PC-ECG module, which has the *USB cable* label, into the free USB port of the PC or of the USB hub with the external power source. If it is for the first time, the driver installation procedure will run automatically (refer to chapter 5.1.1).
6. Install the VARICARD-KARDi application software (see chapter 3.2).
7. Connect ECG electrodes to the ECG connectors (see chapter 4.3).
8. Read the "VARICARD-KARDi software. User's Manual" document and use the VARIAARD-KARDi software to operate with KARDi2/4.
9. Place the ECG electrodes to the patients' wrists and ankles and start a new examination.

3.1.1 Driver first time installation

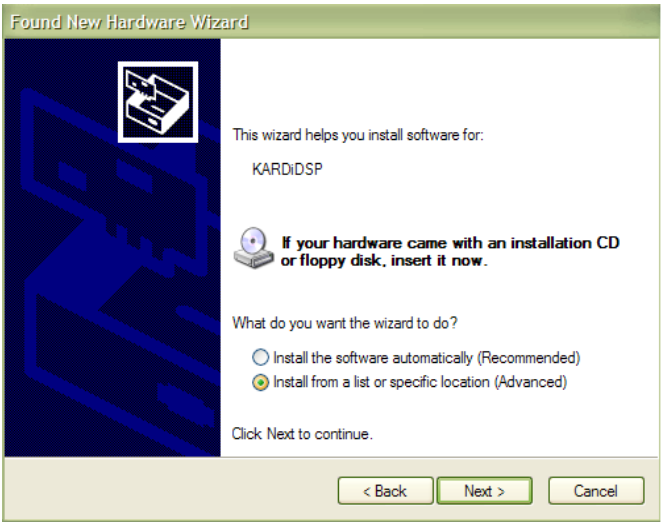
After first connection KARDi2/4 to PC (see chapters 4.1 and 4.2.) by USB cable, Windows will show the message *Found new hardware* and start the wizard dialog *Found New Hardware Wizard* for new device installation.

The dialog windows for Windows XP OS are shown below. For other version of Windows OS the dialog may be different.

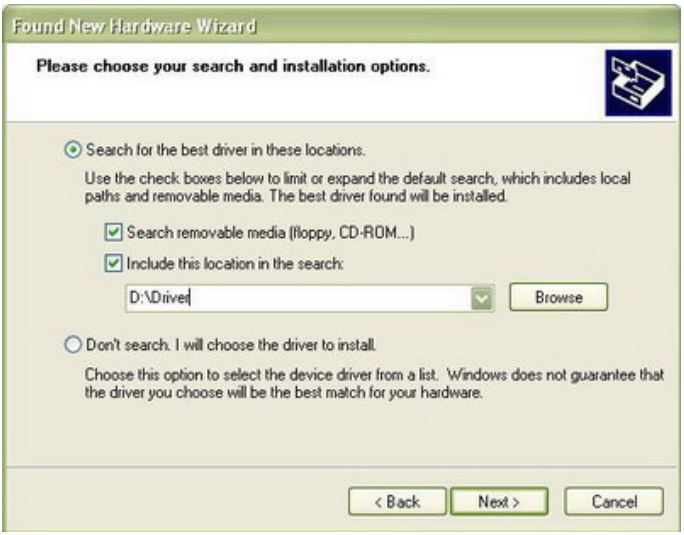
1. When Windows asks to connect to Windows Update, select *No, not this time* and the press *Next* button.



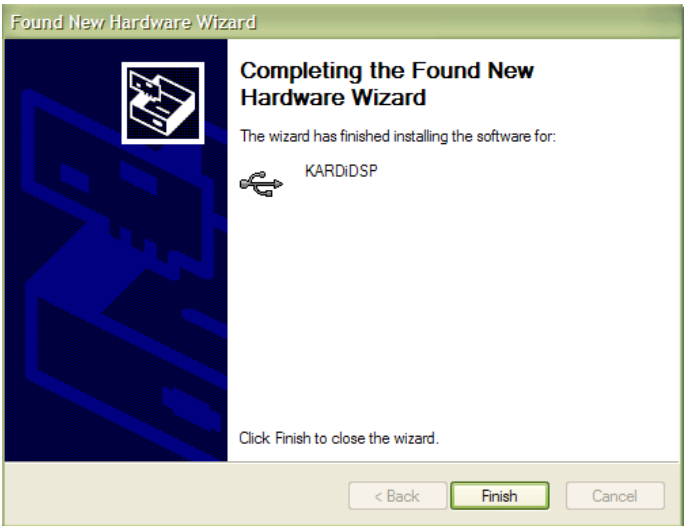
2. Windows will ask to install software automatically or from specific location. Select *Install from a specific location* and press *Next*.



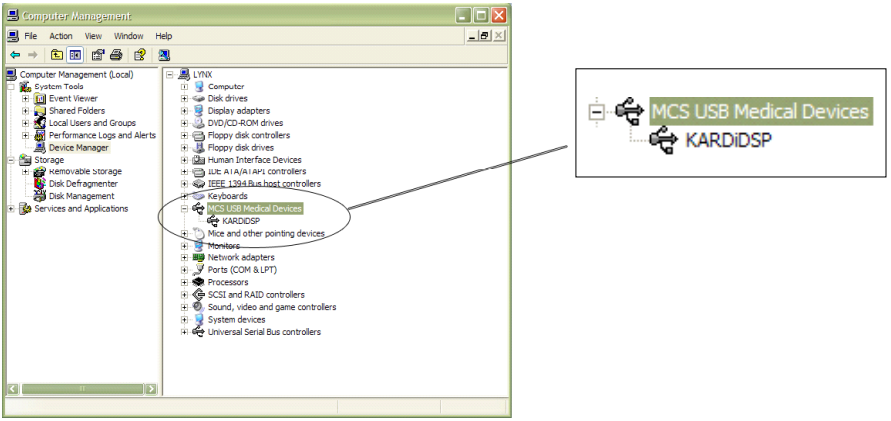
3. Select *Search for the best driver in these locations* and check *Include this location in the search*. Use *Browse* button to select directory where the driver's files are located (for example – D:\Driver) and press *Next*.



4. Windows will show the installation progress for driver's files within few seconds. At the end of installation press *Finish* button.



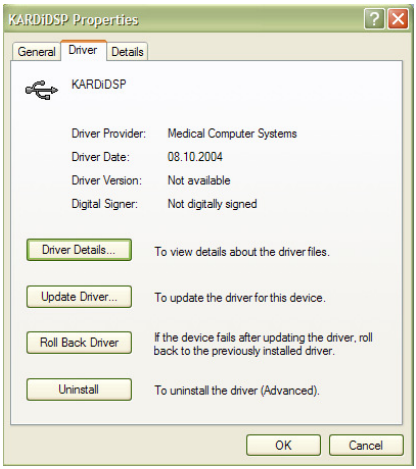
5. To check that the driver installation was successful verify that in the Device Manager the KARDiDSP appears under the MCS USB Medical Devices.



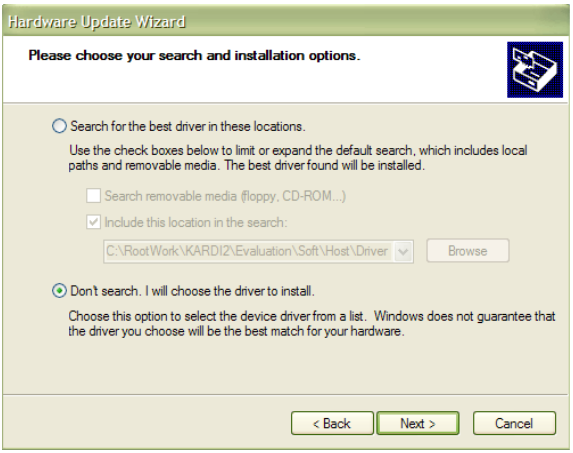
3.1.2 Driver update

For updating the driver double-click on the KARDiDSP device in the *Device Manager*. From the dialog select *Driver* property page and press the *Update Driver…* button.

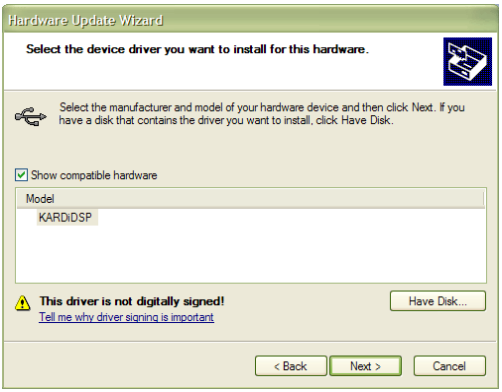
1. Alternatively, right-click on the KARDiDSP in the Device Manager and then select *Update Driver* from the context menu.



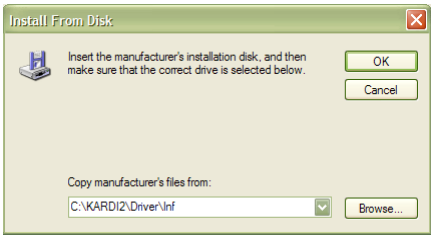
2. Then follow the *Hardware Update Wizard* and perform the same steps as during the first time installation. After getting to the following dialog select *Don't search. I will choose the driver to install*. Press *Next* button.



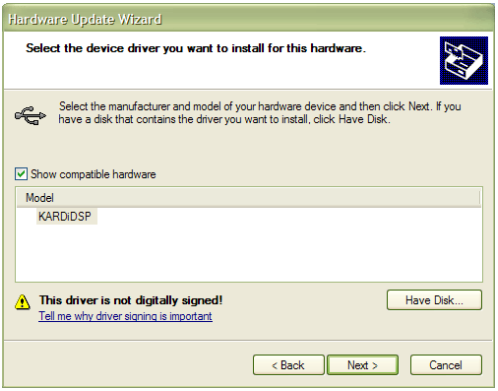
3. Press the *Have Disk…*button.



4. Then select location of the driver's files and press *OK*.



5. Then press *Next* button to start the installation process and wait till the finish dialog will appear.



3.2 Software installation and operation

The installation description of the VARICARD-KARDi software you can find in the applicable document "VARICARD-KARDi software. User's Manual". This document includes the operation documentation too.

3.3 The PC-ECG module fixation

For fixating the KARDi2/4 PC-ECG module on the surface use the special fastener which consists of continuous strips of plastic backing, with plastic mushroom shaped stems protruding up from the backing strip.

The first part of the fastener you can find on the back side of the KARDi2/4. The second part of the fastener is a substrate which can be found in the package.

The substrate has a protective liner. Remove the protective liner and press firmly onto the substrate for full surface contact. All surfaces must be clean, dry, and free of oil, grease, dust etc. The special fastener is disposable and permanent. Be attentive at a choice of an attachment place of the fastener!

When two pieces of the fastener are pressed together, the mushroom heads interlock with one another with an audible snap. To open, simply pull apart.

4. External components

4.1 Safety with system

For connecting the KARDiVAR system with other devices (computers and peripherals – printers, scanner etc) use the IEC60601-1-1 standard about safety requirements of medical electrical systems.

The system is typically used inside the PATIENT ENVIRONMENT (area near 1.5 meters around the patient, see pic.3), that is why all the other devices used with the system should be medical and meet the requirements of the IEC60601-1 standard (for example, PC Advantech POC-174).

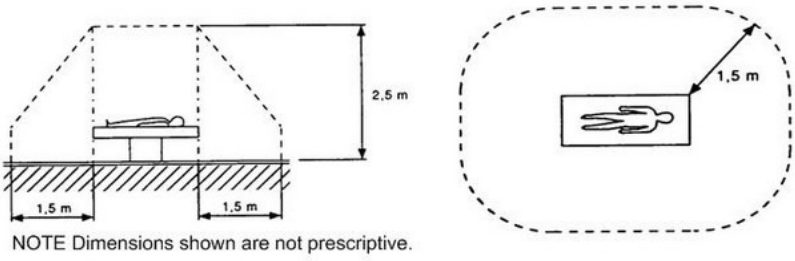


Fig 3 Example of the PATIENT ENVIRONMENT

If non-medical devices are connected to the system via USB and if it is inside the PATIENT ENVIRONMENT then:

1. **all devices** have to be connected to the medical (IEC60601-1) isolation transformer (transformers) with sufficient power supply (for example, AEL Group MIT Medical Isolation Transformers) or
2. **all devices** should be powered from internal energy sources.

However, the PC-ECG module has minimum 3 meters cable to PC with USB connector fixation and touch protection construction. The isolation transformer may not be used if the guaranteed minimal distance to any non-medical device, which meet the requirements of the IEC60601-1-1 standards, will be more than 1.5 meters (outside PATIENT ENVIRONMENT).

4.2 Computer and peripheral devices

Connected computer, as well as others peripheral devices, like printers, must have CE mark and comply with the safety standard for office machines (DIN VDE 0805 or EN60950 or IEC950 or any).

Computer must conform to minimal requirements:

- CPU with equivalent performance not less than Intel Celeron1000MHz.
- Run under Microsoft Windows XP OS.
- Has two free USB1.1 or compatible port.

Make sure that all the latest updates for the Windows OS or its applications, and that the latest USB patches or drivers made by the PC's or system board's developers, are installed on the PC.

4.3 ECG electrodes and electroconductive gels/pastes

For ECG acquisition the ECG electrodes must have the CE mark and the maximum polarization voltage less 300 mV should be used. These electrodes (or wire to electrode) must have the 4 mm socket for connection. For example, the FIAB F9024 (nickel-silver) or F9024SSC (nickel-silver chloride) clamp electrodes may be used.

Other types of electrode connectors can be used by adapter (3 mm socket, snap type, etc). For example, the FIAB PG922/4T snap adapter may be used for disposable electrode connection.

The electroconductive gel/paste used for the ECG acquisition must have the CE mark. For example, NUPREP EEG & ECG Skin Prepping Gel.

5. Malfunctions and their correction

The possible malfunctions and actions for their correcting are in the following table.

Malfunction	Probable reason	Corrective actions
The CD disk cannot be read by the CD-ROM.	The CD disk became dusty.	Extract the CD disk from the CD-ROM and carefully clean the dick with the cleaning based on the alcohol. If the malfunction is not corrected contact the manufacturer representative.
The *Start* button  is not active or by pressing this button there is a message on an error.	The PC-ECG module is not plugged to the PC. The driver is not installed.	Check the USB cable connection. Make sure that the PC-ECG module KARDi2/4 is plugged into the USB hub with the external source of power. Install the driver (see chapter 3.1.1). If the driver is installed - update it (see chapter 3.1.2). Restart the program.
The indicator "Mode" is red.	The error occurred.	Replug the PC-ECG module. Reinstall the system driver. If the malfunction is not corrected contact the manufacturer representative.
The MCS USB Medical Devices is not appeared in the Computer management. The KARDiDSP is not displayed in the Device Manager under the MCS USB Medical Devices.	The connection between PC and PC-ECG module failure. The system driver is not installed.	Check the connection between PC and PC-ECG module, or replug the PC-ECG module. Install the system driver. If the malfunction is not corrected contact the manufacturer representative.
The data analysis takes more time than 1 minute.	The VARICARD-KARDi software has been run with the concurrently running programs (especially with the antivirus monitors).	Close the other running programs, especially the antivirus monitors.

Malfunction	Probable reason	Corrective actions
All (or one) of the ECG signals are not displayed on the screen.	The electrodes (or the electrode of this lead) are not connected to the patient. PC-ECG module failure.	Check the electrode cable's connection. Check the electrode cable's fixation in the electrode. Check the connection between the electrode and the patient. If the malfunction is not corrected contact the manufacturer representative.
All (or one) of the ECG signals are very noisy.	The electrodes (or one electrode) are not greased with the electroconductive paste/gel.	Grease the electrodes (or one needed electrode) with the electroconductive paste/gel. Operate the system in the prescribed conditions. Read the Warning about conditions of system's operating.

6. Specifications

6.1 Main functions

Function	Value
ECG acquisition	The ECG acquisition of the 6 standard leads (I, II, III, aVR,aVL, aVF) by KARDi2/4 PC-ECG module.
Stress level indicator*	Stress level evaluation by a heart rate variability analysis as a result of calculating IRSA
Results of heart rate variability analysis*	Heart rate variability visualization (graphic). Basic heart rhythm variability parameters (table). Heart rhythm systems regulation status (table).
Analysis conclusion*	The medical and physiological conclusions about functional states of autonomic regulation system on the basic of prenosological principles.

*) For more detail see "VARICARD-KARDi software. User's Manual".

6.2 KARDi2/4 PC-ECG module

Parameter	Value
Number of channels	The KARDiVAR system has 3 monopolar channels. The ECG leads are calculated on the PC by VARICARD-KARDi software
Analog front end	DC amplifiers
Input range (effective resolution for 500Hz output data rate)	±410 mV (2 uV)
Defibrillator protection	on base semi-conductors elements
Input DC impedance	greater 70 MOhm according to N electrode
Check electrode connection	Checking connection during registration by measure of DC offset
Analog-to-digital conversion	Sigma-delta modulation with frequency 2048kHz simultaneously on all channels, a digital filtration and decimation up to frequency 16kHz

Parameter	Value
Digital signal processing	Filtration and decimation up to 500 Hz output data rate (20-bit resolution). Internal low pass filters has the -3 dB level on 150 Hz and 5% level on 100 Hz accordingly
Connectors type for electrode	4 mm banana jacks
Galvanic isolation	Reinforced according to IEC60601-1 from PC side
Power line	USB
Voltage	+5 V ± 10%
Maximal current in active mode	less 280 mA
Computer Interface	USB1.1 (USB 2.0), full speed mode, plug-and-play support
Status indicators and modes	Bi-color LEDs indication: • green – no error, active mode. The indicator is burning green during the new examination's making • red – error occurred
USB cable	Min length 3 m, fixed to module
Electrode cable's length	not less than 140 cm
Dimensions of enclosure	100x65x28 mm
Weight with cables	less 350 gram
Working temperature	+10ºC…+35ºC
Storage temperature	+5ºC...+40ºC
Transportation temperature	-30ºC...+50ºC
Humidity	up to 97% without condensation
Mechanical resistance	According to IEC 60601-1

6.3 Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The KARDiVAR system is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The KARDiVAR system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The KARDiVAR system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity
The KARDiVAR system is intended for use in the electromagnetic environment specified

below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	
	±1 kV for input/output lines	±1 kV for input/output lines	
Surge IEC 61000-4-5	±1 kV differential mode	Not applicable	
	±2 kV common mode	Not applicable	
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle	Not applicable	
	40 % *U*T (60 % dip in *U*T) for 5 cycles	Not applicable	
	70 % *U*T (30 % dip in *U*T) for 25 cycles	Not applicable	
	<5 % *U*T (>95 % dip in *U*T) for 5 sec	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity
The KARDiVAR system is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the KARDiVAR system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.33\sqrt{P}$ 800 MHz to 2,5 GHz

where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KARDiVAR system is used exceeds the applicable RF compliance level above, the KARDiVAR system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the KARDiVAR system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the KARDiVAR system

The KARDiVAR system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KARDiVAR system can help prevent electromagnetic interference by maintaining a minimum distance between

portable and mobile RF communications equipment (transmitters) and the KARDiVAR system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = \frac{3.5}{3}\sqrt{P}$	**80 MHz to 800 MHz** $d = \frac{3.5}{3}\sqrt{P}$	**800 MHz to 2,5 GHz** $d = \frac{7}{3}\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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